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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,338	05/30/2001	Sui-Po Zhang	ORT-1440	7714

27777 7590 05/21/2003

AUDLEY A. CIAMPORCERO JR.  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/21/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,338

Applicant(s)

ZHANG ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Claims 1-10 are pending in the present application. This Office action is in response to Paper No. 8, filed 4 March 2003.

#### *Election/Restrictions*

Applicant's election without traverse of Group I, claims 1-10, in Paper No. 8 is acknowledged. Claim 11, drawn to Group II was cancelled by amendment in Paper No. 8.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Bertelli et al. (US 2003/0073132 A1) or Johns et al. (WO 00/20450) in view of Gotti et al. (Differentiation Vol. 34 1987).

Bertelli et al. teach a method for screening compounds wherein a  $\alpha 2\delta$  subunit of the  $\text{Ca}^{2+}$  channel is contacted with a compound of interest and a labeled compound, such as [ $^3\text{H}$ ]gabapentin, and the level of binding of the labeled compound is measured with and without the compound of interest. See column 1, paragraph [0012] – paragraph [0026].

Johns et al. teach a method wherein a  $\alpha 2\delta$  subunit polypeptide is contacted with a compound of interest and wherein the complexes formed between the polypeptide and the

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compound of interest is measured. See page 9, lines 24 –31. The method may further comprise administering a compound, such as gabapentin, that competes for binding with the  $\alpha 2\delta$  subunit polypeptide. The affect the compound of interest has on the binding of the competing compound, *e.g.* gabapentin, is measured. See page 10, lines 10-30 and page 11, line 2. Neither Bertelli et al. nor Johns et al. teach a method wherein the sample containing the  $\alpha 2\delta$  subunit is a neuroblastoma cell membrane sample obtained following incubation with BrdU.

Gotti et al. teach neuroblastoma, IMR-32 cells incubated with BrdU have an affect on voltage dependant channels, including  $\text{Ca}^{2+}$  channels. See page 144 and 153.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a sample comprising cell membrane or cell membrane fragment of neuroblastoma cells as a source of the  $\alpha 2\delta$  subunit of the voltage dependent calcium channel. The ordinary skilled artisan would have been motivated to successfully use a cell membrane sample from a neuroblastoma cell line incubated with BrdU because it would be a useful model of a neuronal cell type, the sertotnergic cell. See Gotti et al. page 154, column 1. The use of these cell types would allow for the identification of compounds specific to the  $\alpha 2\delta$  subunit of a sertonergic cell. Therefore, the invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (b) recites the limitation "the cell membrane." It is unclear whether this limitation refers to the binding of gabapentin to the  $\alpha 2\delta$  subunit of the cell membrane sample or the binding of gabapentin to the cell membrane itself.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
May 18, 2003

  
JAMES KETTER  
PRIMARY EXAMINER